

REMARKS

Claim Status

Claims 1, 3 and 7-27 are pending in the present application. No additional claims fee is believed to be due.

Claim 1 has been amended to further define the present invention wherein the zinc-containing layered material is selected from the group consisting of basic zinc carbonate, zinc carbonate hydroxide, hydrozincite, zinc copper carbonate hydroxide, aurichalcite, copper zinc carbonate hydroxide, rosasite, phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double salts and mixtures thereof. Support for this amendment is found in Claim 14, as originally filed, and now canceled. Claim 15 has been amended to depend from Claim 1, rather than Claim 14, which is now canceled.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejection Under 35 USC §102(b) Over WO 01/00151 (Gavin et al.)

Claims 1, 3, 7 -13 and 18-25 have been rejected under 35 USC §102(b) as being anticipated. WO 01/00151 to Gavin et al (hereinafter "Gavin et al.") as evidenced by the Wikipedia Zinc Oxide.

Gavin et al. discloses topical compositions for the treatment of microbial infections on the skin or scalp. Specifically, the composition of Gavin et al. includes from about 0.001% to about 10% by weight of the composition, of an anti-microbial active selected from the group consisting of polyvalent metal salts of pyrrhione, from about 0.001% to about 10%, by weight of the composition, of a metal ion source selected from the group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts and mixtures thereof and a topical carrier for the anti-microbial active and the metal salt.

The present invention, as currently amended, is directed to a personal care composition comprising from about 0.001% to about 5% of a zinc-containing layered material selected from the group consisting of basic zinc carbonate, zinc carbonate hydroxide, hydrozincite, zinc copper carbonate hydroxide, aurichalcite, copper zinc carbonate hydroxide, rosasite,

phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double salts and mixtures thereof; from about 10% to about 50% of a surfactant including a surfactant with an anionic functional group; from about 0.01% to about 5% of a pyrithione or a polyvalent metal salt of a pyrithione; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15%.

By this amendment, claim 1 has been amended to limit that claim by incorporating the subject matter of original Claim 14. Gavin et al. does not disclose any of the zinc-containing layered materials as recited in the Markush group of original Claim 14. In fact, Claim 14 was not rejected over Gavin et al. under 35 USC 102. Therefore, this amendment renders the 102 rejection moot.

In light of the above remarks, it is requested that the Examiner reconsider and withdraw this rejection under 35 USC §102(b).

Rejection Under 35 USC §102(b) Over US 5,227,156 (Wiese)

Claims 1, 3, 7, 8-13, 20 and 21 have been rejected under 35 USC §102(b) as being anticipated. US 5,227,156 to Wiese (hereinafter “Wiese”) as evidenced by the Wikipedia Zinc Oxide.

Wiese discloses that the activity of a thiazolinone preservative, in an anti-dandruff shampoo containing pyrithione, is maintained by adding a stabilizer comprising a zinc compound. Specifically, Wiese discloses an aqueous anti-dandruff shampoo comprising up to about 40% of a surfactant, from about 0.1% to about 2% zinc pyrithione, from about 1 to about 30 ppm of a preservative selected from the group consisting of 5-chloro-2-alkyl-4-isothiazolin-3-one, 2-alkyl-4-isothiazolin-3-one, wherein the alkyl is selected from the group consisting of methyl, ethyl, butyl, propyl and mixtures thereof, from about 0.001% to about 1% of a preservative stabilizer comprising a zinc compound selected from the group consisting of a zinc salt of an organic acid, a zinc salt of an inorganic acid, zinc oxide, zinc hydroxide, and mixtures thereof, and the balance comprising water.

The present invention, as currently amended, is directed to a personal care composition comprising from about 0.001% to about 5% of a zinc-containing layered material selected from

the group consisting of basic zinc carbonate, zinc carbonate hydroxide, hydrozincite, zinc copper carbonate hydroxide, aurichalcite, copper zinc carbonate hydroxide, rosasite, phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double salts and mixtures thereof; from about 10% to about 50% of a surfactant including a surfactant with an anionic functional group; from about 0.01% to about 5% of a pyrithione or a polyvalent metal salt of a pyrithione; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15%.

By this amendment, claim 1 has been amended to limit that claim by incorporating the subject matter of original Claim 14. Wiese does not disclose any of the zinc-containing layered materials as recited in the Markush group of original Claim 14. In fact, Claim 14 was not rejected over Wiese under 35 USC 102. Therefore, this amendment renders the 102 rejection moot.

In light of the above remarks, it is requested that the Examiner reconsider and withdraw this rejection under 35 USC §102(b).

Rejection Under 35 USC §103(a) Over WO 01/00151 (hereinafter “Gavin et al.”) in view of EP 1145707 (hereinafter “Iwai et al.”) or WO 96/25913 (hereinafter “Bhat et al.”)

Claims 1, 3 and 7-27 have been rejected under 35 USC §103(a) as being unpatentable over WO 01/00151 (hereinafter “Gavin et al.”) in view of EP 1145707 (hereinafter “Iwai et al.”) or WO 96/25913 (hereinafter “Bhat et al.”).

The Office Action asserts that Gavin et al. do not expressly teach a composition comprising a zinc salt basic zinc carbonate. The Office Action further asserts that the deficiency in Gavin et al. is cured by the teachings of Iwai et al. or Bhat et al. It is further asserted that one of ordinary skill in the art would have been motivated to do this because Gavin et al. suggest adding zinc salts to the composition by not specifically basic zinc carbonate and Iwai et al. or Bhat et al. cure this deficiency by teaching that basic zinc carbonate is suitable for external compositions. Applicants respectfully traverse this rejection.

Gavin et al. discloses a topical composition for the treatment of antimicrobial infections on the skin or scalp which includes a polyvalent metal salt of pyrithione, such as zinc

pyrithione and a metal ion source. According to Gavin et al. the metal ion source can be a zinc salt. Suitable zinc salts are listed at page 7, first paragraph of Gavin et al. None of the zinc-containing layered materials as recited in instant claim 1 are included in the list. In fact, Gavin et al. is completely silent as to the use of any of these zinc-containing layered materials for any purposes. In this regard, the Office Action cites Iwai et al. and Bhat et al. and asserts that one skilled in the art would add the basic zinc carbonate disclosed in Iwai et al. or Bhat et al. to the composition disclosed in Gavin et al. to allegedly arrive at the claimed invention. Applicants respectfully traverse the rejections.

Iwai et al. discloses compositions for external use which contain a zinc compound, in particular, a composition for external use which contains a zinc compound and a thiol compound. Although Iwai et al. discloses at paragraph 14 that basic zinc carbonate is a suitable zinc compound for patentees' purposes, the reference does not provide any motivation to select basic zinc carbonate from a long list of zinc compounds and incorporate it in the composition disclosed in Gavin et al. Indeed, Iwai et al. implicitly teaches away from adding basic zinc carbonate to a composition containing zinc pyrithione. This is so because Iwai et al. lists basic zinc carbonate and zinc pyrithione as alternative zinc compounds which may be incorporated into the compositions disclosed therein. In other words, Iwai et al. teaches that if one zinc compound is employed, that is sufficient. Iwai et al. does not suggest the use of the zinc compounds in combination. In view of this teaching, one skilled in the art would not be motivated to add basic zinc carbonate to a composition that already contains a zinc compound such as zinc pyrithione. Accordingly, Iwai et al. does not provide any motivation for one skilled in the art to add basic zinc carbonate to the compositions disclosed in Gavin et al., which contains zinc pyrithione.

Gavin et al. does not provide any motivation either since the reference is completely silent about using zinc-layered materials as recited in the instant claims for any purposes. Accordingly, applicants respectfully submit that there is no motivation to combine Gavin et al. and Iwai et al. Further, Applicants submit that even if one did combine these two references, one would arrive at a composition containing basic zinc carbonate and a pyrithione salt other than zinc pyrithione, which is different from what is recited in the instant claims.

Bhat et al. relates to the preparation and the use of zinc hydroxycarbonate as antimicrobial agent in personal care products. The reference discloses that zinc hydroxycarbonate shows synergistic antimicrobial activity with detergents such as sodium lauryl sulphate. Example 4 of the Bhat et al. discloses a composition containing 2.5% of sodium lauryl sulphate and 2.0% of zinc hydroxycarbonate. The ratio of surfactant to zinc hydroxycarbonate can be calculated to be 1.25:1.

Applicants submit that there is no motivation to combine Gavin et al. and Bhat et al. In addition, even if one skilled in the art did combine Gavin et al. and Bhat et al., one would arrive at a composition containing a surfactant and zinc hydroxycarbonate at a ratio of 1.25:1 to achieve the synergistic effect disclosed in Bhat et al., rather than the instantly claimed a composition wherein the ratio of surfactant to zinc-containing layered material is greater than or equal to 2 to 1. Accordingly, the rejection is untenable and should be withdrawn.

Double Patenting

1) & 2). Claims 1, 3, 4, 7-17 and 23-25 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1, 8, 9, 11, 12, 14-17, 21 and 23-25 of copending U.S. Application No. 10/803,126. Claims 1, 3, 7-22 and 25 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1, 2, 8-12, 16-32 and 34-39 of copending Application No. 11/602,770. These 2 co-pending applications are jointly owned by The Procter & Gamble Company and Arch Chemicals, Inc. As all of the rejections are provisional, Applicants will respond if and when any allowable subject matter is identified. Therefore, Applicants requests that the provisional, obvious-type double patenting rejections be held in abeyance, until indication of allowable subject matter.

3) Claims 1, 3, 7-22 and 25 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1, 2, 9, 13-30, 35 and 17 of copending Application No. 11/890,684.

Claim 1 of the Application 11/890,684 is directed to a composition comprising an effective amount of a particulate zinc material; an effective amount of a surfactant including a surfactant with an anionic functional group; an effective amount of a pyrithione or a polyvalent metal salt of a pyrithione; from about 0.025% to about 5% by weight of a water soluble or dispersible, cationic, non-crosslinked, conditioning homopolymer having a cationic charge density of from about 2 meq/gm to about 10 meq/gm; and from about 20% to about 95% of an aqueous carrier, by weight of said composition.

In contrast, the instant invention is directed to a composition comprising from about 0.001% to about 5 % of a zinc-containing layered material selected from the group consisting of basic zinc carbonate, zinc carbonate hydroxide, hydrozincite, zinc copper carbonate hydroxide, aurichalcite, copper zinc carbonate hydroxide, rosasite, phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double salts and mixtures thereof; from about 10 % to about 50% of a surfactant including a surfactant with an anionic functional group; from about 0.01% to about 5% of a pyrithione or a polyvalent metal salt of a pyrithione; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15% and further wherein the ratio of surfactant to zinc-containing layered material is greater than or equal to 2 to 1.

The currently claimed invention is not directed to a composition containing from about 0.025% to about 5% by weight of a water soluble or dispersible, cationic, non-crosslinked, conditioning homopolymer having a cationic charge density of from about 2 meq/gm to about 10 meq/gm. Further, the '684 application is not directed to or requires a relative zinc lability of greater than about 15% for a zinc-containing layered material. Yet further, the '684 application does not require the amount of zinc layered material *selected from the group consisting of basic zinc carbonate, zinc carbonate hydroxide, hydrozincite, zinc copper carbonate hydroxide, aurichalcite, copper zinc carbonate hydroxide, rosasite, phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double salts and mixtures thereof* or a ratio of surfactant to zinc layered material of greater than or equal to 2:1. These 2 claim sets are patentably distinct and each of the specification and *data* demonstrate that the determination of liquid crystal phase in the '684 application or the ratio of surfactant to zinc layered material and relative zinc

lability as required in the currently claimed invention are *not a matter of routine optimization*. In the '684 application, the surprising discovery that compositions combining certain water soluble or dispersible, cationic, non crosslinked, deposition polymers in combination with surfactants form microscopically-phase separate lyotropic liquid crystals suspended in an aqueous surfactant phase is clearly patentably distinct. In use, the dispersed, concentrated polymer lyotropic liquid crystal phase provides improved hair and skin conditioning.

Therefore, Applicants respectfully request reconsideration and removal of this double patenting rejection.

4) Claims 1, 3, and 7-25 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1-5, 11-27 and 33-46 of copending Application No. 11/899,106.

Claim 1 of the Application 11/899,106 is directed to a composition comprising an effective amount of a zinc containing material having an aqueous solubility within the composition of less than about 25% by weight at 25°C; from about 5% to about 50% of a surfactant; and from about 40% to about 95% water; wherein the pH of the composition is greater than about 7.

In contrast, the instant invention is directed to a composition comprising from about 0.001% to about 5 % of a zinc-containing layered material selected from the group consisting of basic zinc carbonate, zinc carbonate hydroxide, hydrozincite, zinc copper carbonate hydroxide, aurichalcite, copper zinc carbonate hydroxide, rosasite, phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double salts and mixtures thereof; from about 10 % to about 50% of a surfactant including a surfactant with an anionic functional group; from about 0.01% to about 5% of a pyrithione or a polyvalent metal salt of a pyrithione; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15% and further wherein the ratio of surfactant to zinc-containing layered material is greater than or equal to 2 to 1.

The currently claimed invention is not directed to a composition comprising a zinc containing material having an aqueous solubility within the composition of less than about 25%

by weight at 25°C. In contrast, the currently claimed invention requires the limitation of a zinc-containing *layered material selected from the group consisting of basic zinc carbonate, zinc carbonate hydroxide, hydrozincite, zinc copper carbonate hydroxide, aurichalcite, copper zinc carbonate hydroxide, rosasite, phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double salts and mixtures thereof*. Further, the '106 application claims require that the zinc containing material have an aqueous solubility within the composition of less than about 25% by weight at 25°C. Further, the '106 application does not require a relative zinc lability of greater than about 15% for a zinc-containing layered material, as required in the currently claimed invention. Yet further, the '106 application does not require the amount of zinc containing *layered material selected from the group consisting of basic zinc carbonate, zinc carbonate hydroxide, hydrozincite, zinc copper carbonate hydroxide, aurichalcite, copper zinc carbonate hydroxide, rosasite, phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double salts and mixtures thereof* or a ratio of surfactant to zinc layered material of greater than or equal to 2:1. These two claim sets are patentably distinct.

These 2 claim sets are patentably distinct and the present specification and *data* demonstrate that the determination of the ratio of surfactant to zinc layered material as required in the currently claimed invention are *not a matter of routine optimization*.

Therefore, Applicants respectfully request reconsideration and removal of this double patenting rejection.

5) Claims 1, 3, 7, 8, 12, 13 and 15-17 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1 and 4-7 of copending Application No. 12/029,150 in view of Gavin et al.

Claim 1 of the Application 12/029,150 is directed to a personal care method, comprising the step of topically applying a personal care composition to areas of the body other than the scalp and hair growing therefrom, the personal care composition comprising zinc-containing layered material; and a surfactant with an anionic functional group; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15%.

In contrast, the instant invention is directed to a composition comprising from about 0.001% to about 5 % of a zinc-containing layered material selected from the group consisting of basic zinc carbonate, zinc carbonate hydroxide, hydrozincite, zinc copper carbonate hydroxide, aurichalcite, copper zinc carbonate hydroxide, rosasite, phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double salts and mixtures thereof; from about 10 % to about 50% of a surfactant including a surfactant with an anionic functional group; from about 0.01% to about 5% of a pyrithione or a polyvalent metal salt of a pyrithione; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15% and further wherein the ratio of surfactant to zinc-containing layered material is greater than or equal to 2 to 1.

As now amended, Claim 1 of the instant invention includes the matter of originally filed Claim 14. As Claim 14 has *not* been provisionally rejected on the ground of nonstatutory obvious-type double patenting, this amendment renders this rejection moot.

Further, the currently claimed invention is not directed to a personal care *method*, comprising the step of topically applying a personal care composition to areas of the body *other than the scalp and hair growing therefrom*. In contrast, the currently claimed invention, namely Claims 1, 3, 4, 7, 8, 12, 13 and 15-17 are directed to a personal care composition. Further, the '150 application does not require the amount of zinc containing layered material *selected from the group consisting of basic zinc carbonate, zinc carbonate hydroxide, hydrozincite, zinc copper carbonate hydroxide, aurichalcite, copper zinc carbonate hydroxide, rosasite, phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double salts and mixtures thereof* or a ratio of surfactant to zinc layered material of greater than or equal to 2:1. Yet further, the '150 application does not require a pyrithione or a polyvalent metal salt of a pyrithione, as required in the currently claimed invention. Therefore, these two claim sets are patentably distinct.

Applicants respectfully request reconsideration and removal of this double patenting rejection.

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Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejection under 102(b) and 103(a). Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1, 3 and 7-13 and 15-27 is respectfully requested.

Respectfully submitted,

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